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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,224	06/05/2001	Geert Maertens	2752-45	4458
23117	7590	05/18/2005	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			MARTINELL, JAMES	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/873,224

Applicant(s)

MAERTENS ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 2001 and 25 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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In view of the Appeal Brief filed on February 28, 2005, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no basis in the application as filed for the broad recitation of "8 or more contiguous nucleotides selected from an HCV subtype 3c genomic sequence, wherein said polynucleic acid sequence is capable of hybridizing to HCV type 3c, but not another type or subtype of HCV; or the complement of said polynucleic acid, wherein said polynucleic acid contains at least one

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genotype 3c-specific nucleotide" (*e.g.*, claim 24). The instant application does not disclose or teach that the entire HCV type 3c genome may be used, but rather discloses only portions of the HCV type 3c genome to be of use in specific probe and priming assays. The amendments to the claims that contain new matter were filed on August 25, 2003. This is a new ground of rejection.

Claims 24-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed April 25, 2003, page 6, first full paragraph and Office action mailed October 13, 2004, item 5). The instant application does not teach one of skill in the art how to make and use oligonucleotide probes or primers with the claimed properties of specificity of hybridization resulting from the sequences that the various HCV types and subtypes have in common as is evidenced by the Figures in the application. The use of long probes will not provide specific hybridization because of the increasing stabilization. For example, see Kennell (*Progr. Nucl. Acid Res. Mol. Biol.* 11: 259-301 (1971)), paragraph bridging pages 260-261 which states that "thermal stability [of a nucleic acid duplex] rises sharply for longer lengths so that, depending on the G+C content, the stability of a complementary duplex of 25-50 nucleotides approaches that of any much longer complex". Thus, probes of length 25-50 nucleotides may approach maximal stability even if there are one or a few mismatches with the target sequences outside of the region of complementarity. In addition, the application does not teach the use of probes as short as 8 nucleotides for specific hybridization to HCV DNA sequences. Wallace et al (*Methods Enzymol.* 152: 432 (1987)) teaches that probes shorter than 14 bases long are not suitable for specific hybridization to DNA. For example, at pages 433-434, Wallace et al states: "Oligonucleotides have a tendency to bind nonspecifically to noncomplementary DNA sequences. This is probably due to an unavoidably low degree of homology of short oligonucleotides to other DNA sequences and is a particular problem with probes shorter than 14 bases long." Finally, the instant application does not teach one of skill in the art how to amplify specific DNA sequences using only one primer (Claims 50-57).

The CAFC in *In re Wands* (*In re Wands*, 8 USPQ2d 1400, Fed Cir. 1988) listed various factors to be considered in determining enablement. They include:

- (1) The quantity of experimentation necessary
- (2) The amount of direction or guidance presented
- (3) The presence or absence of working examples
- (4) The nature of the invention
- (5) The state of the prior art
- (6) The relative skill of those in the art
- (7) The predictability of the art
- (8) The breadth of the claims

Each of these factors is discussed below.

The quantity of experimentation necessary

A great deal of experimentation is necessary in view of the difficulties in using oligonucleotide probes or primers shorter than 14 nucleotides. See the discussion of Wallace et al above. In addition, a great deal of experimentation is necessary in connection with the use of longer probes in a genotype specific nucleic acid molecular hybridization assay. See the discussion of Kennell above.

The amount of direction or guidance presented

The instant application provides no guidance as to which oligonucleotide probes or primers will have the properties required by the claims beyond the few examples disclosed.

The presence or absence of working examples

There are a few working examples disclosed, which is a relatively small number when compared to the large number of oligonucleotide probes possible.

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The nature of the invention

The invention is in the filed of molecular biology.

The state of the prior art

There is no prior art of record.

The relative skill of those in the art

The relative skill of those in the art is high. The person with skill in the art most likely in possession of a Ph.D. degree and at least some post-doctoral research experience.

The predictability of the art

There is no predictability in connection with which of the many possible oligonucleotide probes will be specific to HCV type 3c. The discovery of such probes is empirical in nature.

The breadth of the claims

The claims are very broad in that there is an astronomical number of possible oligonucleotide probes from HCV that have between 8 and 50 nucleotides.

After consideration of all of these factors, the claims are deemed not enabled for their full scope.

Claims 24-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The application does not provide an adequate written description of the claimed invention because no probes with the desired

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properties are described. The discussion in the rejection immediately above is incorporated here. The instant application does not adequately describe in writing the myriad oligonucleotides that may possibly meet the criteria of the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. Only documents such as those intended for use in a personal or telephone interview should be faxed to the examiner's desktop workstation. Any Official Communication to the USPTO should be faxed to (571) 273-8300.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745.

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OFFICIAL FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


James Martinell, Ph.D.
Primary Examiner
Art Unit 1634

5/13/05


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600